

Amir M. Nassihi (SBN: 235936)
anassihi@shb.com
SHOOK, HARDY & BACON L.L.P.
555 Mission Street Suite 2300
San Francisco, California 94105
Telephone: (415) 544-1900
Facsimile: (415) 391-0281

Michael L. Mallow (SBN: 188745)
mmallow@shb.com
Mayela C. Montenegro-Urch (SBN: 304471)
mmontenegro@shb.com
SHOOK, HARDY & BACON L.L.P.
2049 Century Park East, Suite 3000
Los Angeles, California 90067
Telephone: (424) 285-8330
Facsimile: (424) 204-9093

[Additional Counsel on Signature Page]

Attorneys for Defendants
INTERNATIONAL MEDICAL DEVICES, INC.,
MENOVA INTERNATIONAL, INC., GESIVA
MEDICAL, LLC, JAMES J. ELIST, M.D., A
MEDICAL CORPORATION, and DR. JAMES ELIST

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA – EASTERN DIVISION

EDWARD PEÑA and BRANDON MILLER, individually and on behalf of others similarly situated,

Plaintiffs,

v.

INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M. D., a Medical Corporation, and Dr. James ELIST

Defendants.

) Case No. 2:22-cv-03391-SSS (RAOx)

) Judge: Hon. Sunshine S. Sykes

) **DEFENDANTS' ANSWER TO PLAINTIFFS' THIRD AMENDED CLASS ACTION COMPLAINT**

) Complaint Filed: May 25, 2022

) First Am. Compl. Filed: June 15, 2022

) Second Am. Compl. Filed: Jan. 20, 2023

) Third Am. Compl. Filed: July 19, 2023

1 Defendants International Medical Devices, Inc., Menova International, Inc.,
 2 Gesiva Medical, LLC, James J. Elist M.D., A Medical Corporation, and Dr. James
 3 Elist (collectively, “Defendants”), by and through their undersigned counsel, hereby
 4 answer Plaintiffs Edward Peña’s and Brandon Miller’s Third Amended Class Action
 5 Complaint (“TAC”).

6 The numbered paragraphs below correspond with the numbered paragraphs in
 7 the TAC. Any allegation in the TAC that has not been expressly admitted is denied.

8 I. INTRODUCTION

9 1. Defendants deny the allegations of Paragraph 1.

10 2. Defendants admit that Dr. James J. Elist developed a surgical procedure
 11 for implanting the Penuma device. They admit that he has performed thousands of
 12 these procedures, handling patient consults at his clinic in Beverly Hills and
 13 performing penile implant surgeries in an operating room at the Beverly Hills South
 14 Pacific Surgery Center. Defendants deny the remaining allegations in Paragraph 2.

15 3. Defendants admit that Penuma is FDA-cleared for cosmetic
 16 augmentation of the penis. The remaining allegations of Paragraph 3 consist of
 17 argument and legal conclusion to which no response is required. To the extent a
 18 further response is required, Defendants deny the allegations of Paragraph 3.

19 4. Defendants admit that the website www.penuma.com states that the
 20 Penuma is “the first FDA-cleared penile implant for cosmetic [male] enhancement.”
 21 Defendants deny the remaining allegations in Paragraph 4.

22 5. Defendants admit that Plaintiffs bring this action, but deny that they are
 23 entitled to any relief. Defendants deny the remaining allegations of Paragraph 5.

24 II. PARTIES

25 6. Defendants are without sufficient information to admit or deny the
 26 allegations of Paragraph 6. To the extent a further response is required, Defendants
 27 deny the allegations of Paragraph 6.

1 7. Defendants are without sufficient information to admit or deny the
2 allegations of Paragraph 7. To the extent a further response is required, Defendants
3 deny the allegations of Paragraph 7.

4 8. Defendants deny that IMD is located at 717 N. Maple Dr., Beverly Hills,
5 CA 90210. Defendants admit the remaining allegations of Paragraph 8.

6 9. Defendants admit the allegations of Paragraph 9.

7 10. Defendants admit the allegations of Paragraph 10.

8 11. Defendants admit the allegations of Paragraph 11.

9 12. Defendants admit the allegations of Paragraph 12.

10 **III. JURISDICTION AND VENUE**

11 13. The allegations of Paragraph 13 consist of argument and legal
12 conclusions to which no response is required. To the extent a further response is
13 required, Defendants deny the allegations of Paragraph 13.

14 14. The allegations of Paragraph 14 consist of argument and legal
15 conclusions to which no response is required. To the extent a response is required,
16 Defendants admit the allegations of Paragraph 14.

17 15. The allegations of Paragraph 15 consist of argument and legal
18 conclusions to which no response is required. To the extent a response is required,
19 Defendants deny the allegations of Paragraph 15.

20 16. The allegations of Paragraph 16 consist of argument and legal
21 conclusions to which no response is required. To the extent a response is required,
22 Defendants deny the allegations of Paragraph 16.

23 17. The allegations of Paragraph 17 consist of argument and legal
24 conclusions to which no response is required. To the extent a response is required,
25 Defendants deny the allegations of Paragraph 17.

26 **IV. JOINT ENTERPRISE LIABILITY**

27 18. Defendants deny the allegations of Paragraph 18.

28 19. Defendants deny the allegations of Paragraph 19.

20. Defendants deny the allegations of Paragraph 20.

21. The allegations of Paragraph 21 consist of argument and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 21.

22. Defendants deny the allegations of Paragraph 22.

V. STATEMENT OF FACTS

23. Defendants are without sufficient information to admit or deny the allegations of Paragraph 23. To the extent a further response is required, Defendants deny the allegations of Paragraph 23.

24. Defendants are without sufficient information to admit or deny the allegations of Paragraph 24. To the extent a further response is required, Defendants deny the allegations of Paragraph 24.

25. Defendants are without sufficient information to admit or deny the allegations of Paragraph 25. To the extent a further response is required, Defendants deny the allegations of Paragraph 25.

26. Defendants are without sufficient information to admit or deny the allegations of Paragraph 26. To the extent a further response is required, Defendants deny the allegations of Paragraph 26.

27. Defendants are without sufficient information to admit or deny the allegations of Paragraph 27. To the extent a further response is required, Defendants deny the allegations of Paragraph 27.

28. Defendants admit that Dr. Elist consulted with Mr. Peña in October 2020, but deny that this was the first contact Mr. Peña had with Dr. Elist's office. Defendants admit that Mr. Pena filled out an eligibility questionnaire in June 2020 and that Mr. Peña met with other employees of James J. Elist MD, a Medical Corporation. Defendants admit that Dr. Elist performed surgery to implant the Penuma device in Mr. Peña's body. Defendants deny the remaining allegations of Paragraph 28.

29. Defendants deny the allegations of Paragraph 29.

1 30. Defendants are without sufficient information to admit or deny the
2 allegations of Paragraph 30. To the extent a further response is required, Defendants
3 deny the allegations of Paragraph 30.

4 31. Defendants are without sufficient information to admit or deny the
5 allegations of Paragraph 31. To the extent a further response is required, Defendants
6 deny the allegations of Paragraph 31.

7 32. Defendants are without sufficient information to admit or deny the
8 allegations of Paragraph 32. To the extent a further response is required, Defendants
9 deny the allegations of Paragraph 32.

10 33. Defendants are without sufficient information to admit or deny the
11 allegations of Paragraph 33. To the extent a further response is required, Defendants
12 deny the allegations of Paragraph 33.

13 34. Defendants are without sufficient information to admit or deny the
14 allegations of Paragraph 34. To the extent a further response is required, Defendants
15 deny the allegations of Paragraph 34.

16 35. Defendants are without sufficient information to admit or deny the
17 allegations of Paragraph 35. To the extent a further response is required, Defendants
18 deny the allegations of Paragraph 35.

19 36. Defendants are without sufficient information to admit or deny the
20 allegations of Paragraph 36. To the extent a further response is required, Defendants
21 deny the allegations of Paragraph 36.

22 37. Defendants are without sufficient information to admit or deny the
23 allegations of Paragraph 37. To the extent a further response is required, Defendants
24 deny the allegations of Paragraph 37.

25 38. Defendants admit that Mr. Miller contacted Dr. Elist's office in March
26 and April 2019 and that Mr. Miller met with employees of James J. Elist MD, a
27 Medical Corporation in April 2019. Defendants deny the remaining allegations of
28 Paragraph 38.

1 39. Defendants admit that Dr. Elist performed surgery to implant a Penuma
2 device in Mr. Miller's body in November 2019. Defendants deny the remaining
3 allegations of Paragraph 38.

4 40. Defendants admit the allegations of Paragraph 40.

5 41. Defendants are without sufficient information to admit or deny the
6 allegations of Paragraph 41. To the extent a further response is required, Defendants
7 deny the allegations of Paragraph 41.

8 42. Defendants are without sufficient information to admit or deny the
9 allegations of Paragraph 42. To the extent a further response is required, Defendants
10 deny the allegations of Paragraph 42.

11 43. Defendants admit that Dr. Elist performed surgery to implant a Penuma
12 device in Mr. Miller's body in November 2020. Defendants deny the remaining
13 allegations of Paragraph 43.

14 44. Defendants are without sufficient information to admit or deny the
15 allegations of Paragraph 44. To the extent a further response is required, Defendants
16 deny the allegations of Paragraph 44.

17 45. Defendants admit that Dr. Elist performed surgery to remove a Penuma
18 device from Mr. Miller's body in March 2021. Defendants deny the remaining
19 allegations of Paragraph 45.

20 46. Defendants admit that a Kenalog cycle was part of Mr. Miller's post-
21 removal course of treatment. Defendants are without sufficient information to admit
22 or deny the remaining allegations of Paragraph 46. To the extent a further response is
23 required, Defendants deny those allegations.

24 47. Defendants are without sufficient information to admit or deny the
25 allegations of Paragraph 47. To the extent a further response is required, Defendants
26 deny the allegations of Paragraph 47.

27 48. Defendants are without sufficient information to admit or deny the
28 allegations of Paragraph 48. To the extent a further response is required, Defendants

1 deny the allegations of Paragraph 48.

2 VI. CLASS ALLEGATIONS

3 49. Defendants admit Dr. Elist has received numerous patents related to the
4 Penuma device. Defendants deny the remaining allegations of Paragraph 49.

5 50. Defendants admit that IMD submitted a 510(k) premarket notification on
6 March 15, 2022, which FDA granted on May 13, 2022. IMD's submission and
7 FDA's clearance speak for themselves, and Defendants deny Plaintiffs'
8 characterization of them. Defendants deny that IMD's 510(k) premarket notification
9 was made on May 9, 2022. The remaining allegations consist of argument to which no
10 response is required. To the extent a response is required, Defendants deny the
11 remaining allegations of Paragraph 50.

12 51. FDA's clearance letter and the cited regulation speak for themselves, and
13 Defendants deny Plaintiffs' characterization. Defendants deny that IMD's 510(k)
14 premarket notification was made on May 9, 2022. The remaining allegations consist
15 of argument and legal conclusion to which no response is required. To the extent a
16 response is required, Defendants deny the remaining allegations of Paragraph 51.

17 52. Defendants deny the allegations of Paragraph 52.

18 53. Defendants admit that Dr. Elist is the sole owner and has served as the
19 president of IMD. Defendants further admit that Jonathan Elist is IMD's chief
20 executive officer. Defendants deny the remaining allegations of Paragraph 53.

21 54. Defendants admit the allegations of Paragraph 54.

22 55. Defendants admit that Dr. Elist trains urologists to implant the Penuma.
23 Defendants deny the remaining allegations of Paragraph 55.

24 56. Defendants state that the article and blog posting discussed in Paragraph
25 36 speak for themselves, and Defendants deny Plaintiffs' characterization of them.
26 The remaining allegations of Paragraph 56 consist of argument to which no response
27 is required. To the extent a response is required, Defendants deny the allegations of
28 Paragraph 56.

1 57. Defendants admit the study from 2018, entitled “A Single-Surgeon
2 Retrospective and Preliminary Evaluation of the Safety and Effectiveness of the
3 Penuma Silicone Sleeve Implant for Elective Cosmetic Correction of the Flaccid
4 Penis,” was conducted and published in a peer-reviewed journal. That study and
5 others discussed in Paragraph 57 speak for themselves, and Defendants deny
6 Plaintiffs’ characterization of them. The remaining allegations of Paragraph 37 consist
7 of arguments to which no response is required. To the extent a further response is
8 required, Defendants deny the allegations of Paragraph 57.

9 58. Defendants admit the Penuma device is a medical device that is subject to
10 the Medical Device Amendments of 1976 (“MDA”) to the Food, Drug, and Cosmetic
11 Act (“FDCA”). The remaining allegations of Paragraph 58 consist of argument and
12 legal conclusion to which no response is required. To the extent a further response is
13 required, Defendants deny the allegations of Paragraph 58.

14 59. The allegations of Paragraph 59 consist of argument and legal conclusion
15 to which no response is required. To the extent a response is required, Defendants
16 deny the allegations of Paragraph 59.

17 60. The allegations of Paragraph 60 consist of argument and legal conclusion
18 to which no response is required. To the extent a response is required, Defendants
19 deny the allegations of Paragraph 60.

20 61. The allegations of Paragraph 61 consist of argument and legal conclusion
21 to which no response is required. To the extent a response is required, Defendants
22 deny the allegations of Paragraph 61.

23 62. Defendants admit that National Medical Devices sought FDA clearance
24 to market the Penuma on or about September 1, 2004 and that the FDA granted 510(k)
25 clearance on October 24, 2004. National Medical Devices’ submission and FDA’s
26 clearance speak for themselves. The remaining allegations of Paragraph 62 consist of
27 argument and legal conclusion to which no response is required. To the extent a
28 response is required, Defendants deny the allegations of Paragraph 62.

1 63. Defendants admit that IMD submitted a 510(k) premarket notifications
 2 on December 20, 2016, and December 19, 2018, which FDA granted on February 1,
 3 2017, and January 23, 2019. IMD's submissions and FDA's clearances speak for
 4 themselves, and Defendants deny Plaintiffs' characterization of them and deny that
 5 this paragraph describes all FDA clearances obtained by IMD. The remaining
 6 allegations consist of argument to which no response is required. To the extent a
 7 response is required, Defendants deny the remaining allegations of Paragraph 63.

8 64. Defendants deny the allegations of Paragraph 64.

9 65. The allegations of Paragraph 65 consist of arguments to which no
 10 response is required. To the extent a response is required, Defendants deny the
 11 allegations of Paragraph 65.

12 66. Defendants specifically deny Plaintiffs' allegation that the Penuma is
 13 "neither safe and effective nor FDA-cleared." The remaining allegations of Paragraph
 14 66 consist of argument to which no response is required. To the extent a response is
 15 required, Defendants deny the allegations of Paragraph 66.

16 67. Defendants deny the allegations of Paragraph 67.

17 68. Defendants admit that the Penuma device is marketed on
 18 www.drelist.com by Defendant James J. Elist, MD, a Medical Corporation and on
 19 www.penuma.com by Defendant International Medical Devices, Inc. The websites
 20 speak for themselves, and Defendants deny Plaintiffs' characterization of them. The
 21 remaining allegations consist of argument and legal conclusions to which no response
 22 is required. To the extent a response is required, Defendants deny the remaining
 23 allegations of Paragraph 68.

24 69. The news articles discussed in Paragraph 69 speak for themselves, and
 25 Defendants deny Plaintiffs' characterization of them. Defendants deny the remaining
 26 allegations of Paragraph 69.

27 70. Defendants admit that the Penuma is marketed by Defendant James J.
 28 Elist, MD, a Medical Corporation on www.drelist.com. The website speaks for itself,

1 and Defendants deny Plaintiffs' characterization of it. Defendants deny the remaining
2 allegations of Paragraph 70.

3 71. Defendants deny the allegations of Paragraph 71.

4 72. Defendants deny the allegations of Paragraph 72.

5 73. Defendants deny the allegations of Paragraph 73.

6 74. Defendants deny the allegations of Paragraph 74.

7 75. Defendants deny the allegations of Paragraph 75.

8 76. Defendants deny the allegations of Paragraph 76.

9 77. Defendants deny the allegations of Paragraph 77.

10 78. Defendants deny the allegations of Paragraph 78.

11 79. Defendants deny the allegations of Paragraph 79.

12 80. Defendants deny the allegations of Paragraph 80.

13 81. Defendants deny Plaintiffs' allegations related to the cost of the Penuma
14 device and implantation surgery, the amount paid to IMD, and that "all defendants
15 profit . . . from the sales of the Penuma device." The remaining allegations of
16 Paragraph 81 consist of argument to which no response is required. To the extent a
17 response is required, Defendants deny the allegations of Paragraph 81.

18 82. Defendants admit Dr. Elist has performed thousands of Penuma
19 implantation procedures. Defendants deny the remaining allegations of Paragraph 82.

20 83. Defendants deny the allegations of Paragraph 83.

21 84. Defendants deny the allegations of Paragraph 84.

22 85. Defendants deny the allegations of Paragraph 85.

23 86. Defendants state that the studies cited in Paragraph 86 speak for
24 themselves, and Defendants deny Plaintiffs' characterization of them. Defendants
25 deny the remaining allegations of Paragraph 86.

26 87. Defendants state that the website and study cited in paragraph 87 speak
27 for themselves, and Defendants deny Plaintiffs' characterization of them. Defendants
28 deny the remaining allegations of Paragraph 87.

88. Defendants state that the document cited in paragraph 88 speaks for itself. Defendants deny Plaintiffs' characterization of the document, and further deny the allegations quoted from the document. Defendants deny the remaining allegations of Paragraph 88.

89. Defendants deny the allegations of Paragraph 89.

90. Defendants deny the allegations of Paragraph 90.

91. Defendants deny the allegations of Paragraph 91.

92. Defendants deny the allegations of Paragraph 92.

[Paragraph Under Heading “D. Class Definition” is Missing in TAC]

The allegations of this Paragraph consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of this Paragraph.

93. The allegations of Paragraph 93 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 93.

94. The allegations of Paragraph 94 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 94.

95. The allegations of Paragraph 95 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 95.

96. The allegations of Paragraph 96 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 96.

97. The allegations of Paragraph 97 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 97, including the subparts

98. The allegations of Paragraph 98 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 98.

99. The allegations of Paragraph 99 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 99.

VII. CLAIMS

**COUNT ONE – Violation of California’s False Advertising Law, CAL. BUS. &
PROF. CODE § 17500 (“FAL”)**

100. Defendants incorporate their preceding responses by reference.

101. The allegations of Paragraph 101 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 101.

102. The allegations of Paragraph 102 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 102.

103. The allegations of Paragraph 103 consist of argument and legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 103.

104. Defendants deny the allegations of Paragraph 104.

105. Defendants deny the allegations of Paragraph 105.

106. Defendants deny the allegations of Paragraph 106.

107. Defendants deny the allegations of Paragraph 107.

108. Defendants deny the allegations of Paragraph 108.

109. Defendants deny the allegations of Paragraph 109.

**COUNT TWO – Violation of California’s Consumers Legal Remedies Act, CAL.
CIV. CODE § 1750 *et seq.* (“CLRA”)**

110. Defendants incorporate their preceding responses by reference.

1 111. The allegations of Paragraph 111 consist of argument and legal
2 conclusion to which no response is required. To the extent a response is required,
3 Defendants deny the allegations of Paragraph 111.

4 112. The allegations of Paragraph 90 consist of argument and legal conclusion
5 to which no response is required. To the extent a response is required, Defendants
6 deny the allegations of Paragraph 112.

7 113. Defendants deny the allegations of Paragraph 113.

8 114. The allegations of Paragraph 114 consist of argument and legal
9 conclusion to which no response is required. To the extent a response is required,
10 Defendants deny the allegations of Paragraph 114.

11 115. The allegations of Paragraph 115 consist of argument and legal
12 conclusion to which no response is required. To the extent a response is required,
13 Defendants deny the allegations of Paragraph 115.

14 116. Defendants deny the allegations of Paragraph 116, including subparts.

15 117. Defendants deny the allegations of Paragraph 117.

16 118. Defendants deny the allegations of Paragraph 118, including subparts.

17 119. Defendants deny the allegations of Paragraph 119, including subparts.

18 120. Defendants deny the allegations of Paragraph 120.

19 121. Defendants deny the allegations of Paragraph 121.

20 122. The allegations of Paragraph 122 consist of argument and legal
21 conclusion to which no response is required. To the extent a response is required,
22 Defendants deny the allegations of Paragraph 122.

23 123. Defendants deny the allegations of Paragraph 123.

24 124. Defendants deny the allegations of Paragraph 124.

25 125. Defendants deny the allegations of Paragraph 125.

26 126. Defendants deny the allegations of Paragraph 126.

1 127. The allegations of Paragraph 127 consist of argument and legal
2 conclusion to which no response is required. To the extent a response is required,
3 Defendants deny the allegations of Paragraph 127.

4 128. The allegations of Paragraph 128 consist of argument and legal
5 conclusion to which no response is required. To the extent a response is required,
6 Defendants deny the allegations of Paragraph 128.

7 **COUNT THREE – Violation of California’s Unfair Competition Law, CAL. BUS.
8 & PROF. CODE § 17200 *et seq.* (“UCL”)**

9 129. Defendants incorporate their preceding responses by reference.

10 130. The allegations of Paragraph 130 consist of argument and legal
11 conclusion to which no response is required. To the extent a response is required,
12 Defendants deny the allegations of Paragraph 130.

13 131. The allegations of Paragraph 131 consist of argument and legal
14 conclusion to which no response is required. To the extent a response is required,
15 Defendants deny the allegations of Paragraph 131.

16 132. Defendants deny the allegations of Paragraph 132.

17 133. Defendants deny the allegations of Paragraph 133, including subparts.

18 134. Defendants deny the allegations of Paragraph 134.

19 135. Defendants deny the allegations of Paragraph 135.

20 136. Defendants deny the allegations of Paragraph 136.

21 137. Defendants deny the allegations of Paragraph 137.

22 138. Defendants deny the allegations of Paragraph 138.

23 139. Defendants deny the allegations of Paragraph 139.

24 140. The allegations of Paragraph 140 consist of argument and legal
25 conclusion to which no response is required. To the extent a response is required,
26 Defendants deny the allegations of Paragraph 140.

27 141. The allegations of Paragraph 141 consist of argument and legal
28 conclusion to which no response is required. To the extent a response is required,

1 Defendants deny the allegations of Paragraph 141.

2 **VIII. CONCLUSION AND PRAYER**

3 Defendants deny each and every allegation in the Conclusion and Prayer.

4 **AFFIRMATIVE DEFENSES**

5 Defendants plead the following affirmative defenses. By such pleading,
6 Defendants intend no alteration of burden of proof or burden of going forward with
7 evidence that otherwise exists with respect to any particular issue at law or in equity.
8 Furthermore, that the defenses are pleaded in the alternative does not constitute an
9 admission of liability as to any claim or cause of action or that Plaintiff is entitled to
10 any relief whatsoever.

11 **FIRST AFFIRMATIVE DEFENSE**

12 **(Failure to State a Claim)**

13 1. Plaintiffs' TAC, and each and every purported cause of action therein,
14 fails to state a claim upon which relief can be granted.

15 **SECOND AFFIRMATIVE DEFENSE**

16 **(Preemption)**

17 2. Some or all of the claims made in Plaintiffs' TAC, including claims made
18 on behalf of the proposed putative classes, are barred because they are preempted by
19 federal law and/or regulations.

20 **THIRD AFFIRMATIVE DEFENSE**

21 **(Primary Jurisdiction)**

22 3. Some or all of the claims made in Plaintiffs' TAC, including claims made
23 on behalf of the proposed putative classes, may be barred because of the doctrine of
24 primary jurisdiction.

25 **FOURTH AFFIRMATIVE DEFENSE**

26 **(Accord and Satisfaction)**

27 4. If any persons claiming to be members of the proposed classes have
28 resolved similar or the same claims as those alleged in the TAC, they may be barred

1 from recovery, in whole or in part, on the ground that they are subject to the defense
2 of accord and satisfaction.

3 **FIFTH AFFIRMATIVE DEFENSE**

4 **(Statute of Limitations)**

5. The claims of Plaintiffs and/or members of the proposed classes may be
6 time-barred under the applicable statute of limitations.

7 **SIXTH AFFIRMATIVE DEFENSE**

8 **(Waiver, Estoppel, and/or Laches)**

9. The claims of Plaintiffs and/or members of the proposed classes are
10 barred, in whole or in part, based on the doctrines of waiver, estoppel, and/or laches.

11 **SEVENTH AFFIRMATIVE DEFENSE**

12 **(Failure to Mitigate Damages)**

13. The claims of Plaintiffs and/or members of the proposed classes are
14 barred, in whole or in part, to the extent Plaintiffs and/or members of the proposed
15 classes have failed to mitigate damages and/or have caused some or all of the alleged
16 damage of which they now complain.

17 **EIGHTH AFFIRMATIVE DEFENSE**

18 **(Adequate Remedy at Law)**

19. The claims of Plaintiffs and members of the proposed classes for
20 equitable remedies are barred because Plaintiffs and members of the proposed classes
21 have an adequate remedy at law.

22 **NINTH AFFIRMATIVE DEFENSE**

23 **(Acts of Other Parties)**

24. Any and all violations alleged in the TAC were proximately caused or
25 contributed to by the acts, omissions, or conduct of parties other than Defendants, and
26 for this reason, the TAC fails to state facts sufficient to constitute a cause of action
27 against Defendants. In the alternative, Defendants are entitled to contribution from
28 such other parties or proration of civil penalties or other relief.

1 **TENTH AFFIRMATIVE DEFENSE**

2 **(Set Off)**

3 10. To the extent Plaintiffs and/or members of the proposed classes recoup
4 any damages, such damages are subject to set off and recoupment.

5 **ELEVENTH AFFIRMATIVE DEFENSE**

6 **(Improper Venue)**

7 11. Plaintiffs and/or members of the proposed classes are barred from
8 pursuing their claims within the TAC because venue is improper.

9 **RESERVATION OF RIGHT TO AMEND**

10 Defendants reserve the right to assert additional defenses, counterclaims, cross-
11 claims, or third-party claims as they become known throughout the course of this
12 litigation and may become available under the substantive law of the State of
13 California.

14 WHEREFORE, Defendants ask for the following relief:

- 15 1. For dismissal of Plaintiffs' Third Amended Class Action Complaint with
16 prejudice;
- 17 2. For judgment in favor of Defendants against Plaintiffs;
- 18 3. For the costs of suit herein; and
- 19 4. For such other and further relief as the Court may deem just and proper.

20 **DEMAND FOR JURY TRIAL**

21 Defendants hereby demand a trial by jury on all issues so triable.

1 Dated: August 14, 2023

Respectfully submitted,

2 SHOOK, HARDY & BACON L.L.P.

3 By: /s/ Amir M. Nassihi

4 Amir M. Nassihi

5 Michael L. Mallow

6 Jennifer M. Stevenson

7 Mayela C. Montenegro-Urch

8 Jennifer M. Stevenson (admitted *pro hac
vice*)

9 jstevenson@shb.com

10 Evan D. Montgomery (admitted *pro hac
vice*)

11 emontgomery@shb.com

12 SHOOK, HARDY & BACON L.L.P.

2555 Grand Boulevard

Kansas City, Missouri 64108

Telephone: (816) 474-6550

Facsimile: (816) 421-5547

13 Attorneys for Defendants

14 INTERNATIONAL MEDICAL DEVICES,
15 INC., MENOVA INTERNATIONAL,
16 INC., GESIVA MEDICAL, LLC, JAMES
17 J. ELIST M.D., a Medical Corporation, and
18 DR. JAMES ELIST